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 19 SENORX, INC.

20 UNITED STATES DISTRICT COURT  
 21 NORTHERN DISTRICT OF CALIFORNIA  
 22 SAN JOSE DIVISION

23 HOLOGIC, INC., CYTYC CORP., and	)	CASE NO.: C-08-00133 RMW
24 HOLOGIC L.P.,	)	
25 v.	)	<b>DEFENDANT SENORX, INC.'S</b>
26 Plaintiffs,	)	<b>ANSWER TO COMPLAINT</b>
27 SENORX, INC.,	)	<b>COUNTERCLAIMANT SENORX,</b>
28 v.	)	<b>INC.'S COUNTERCLAIMS FOR</b>
29 Defendant.	)	<b>DECLARATORY JUDGMENT OF</b>
30 SENORX, INC.,	)	<b>PATENT INVALIDITY AND NON-</b>
31 Counterclaimant,	)	<b>INFRINGEMENT</b>
32 v.	)	<b>DEMAND FOR JURY TRIAL</b>
33 HOLOGIC, INC., CYTYC CORP., and	)	Honorable Ronald M. Whyte
34 HOLOGIC L.P.,	)	
35 Counterdefendants.	)	

## **ANSWER TO COMPLAINT**

Defendant SenoRx, Inc. (“SenoRx”), through undersigned counsel, answers the Complaint of Plaintiffs Hologic, Inc., Cytac Corp., and Hologic L.P. (“Plaintiffs”) as follows:

## **ANSWER TO NATURE OF THE ACTION**

1. SenoRx admits that in bringing this action, the Plaintiffs purport to seek damages and injunctive relief arising out of SenoRx's alleged infringement of U.S. Patent Nos. 5,913,813; 6,413,204; and 6,482,142 (the "Patents-In-Suit"). SenoRx denies that it infringes any valid, enforceable claim of any of the Patents-In-Suit, that the Plaintiffs are entitled to any damages or injunctive relief, and any and all other allegations set forth in paragraph 1 of the Complaint.

2. On information and belief, SenoRx admits the allegations set forth in paragraph 2 of the Complaint.

3. On information and belief, SenoRx admits the allegations set forth in paragraph 3 of the Complaint.

4. On information and belief, SenoRx admits the allegations set forth in paragraph 4 of the Complaint.

5. SenoRx admits the allegations set forth in paragraph 5 of the Complaint.

## **ANSWER TO JURISDICTION AND VENUE**

6. The allegations of paragraph 6 of the Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 6 of the Complaint sets forth factual allegations to which a response is required, SenoRx admits that an action for infringement of a United States Patent may arise under 35 U.S.C. § 281, and that jurisdiction for such an action in this Court may be founded on 28 U.S.C. § 1338(a). SenoRx denies any and all other allegations set forth in paragraph 6 of the Complaint.

7. The allegations of paragraph 7 of the Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 7 of the Complaint sets forth factual allegations to which a response is required, SenoRx denies the allegations set forth in paragraph 7 of the Complaint.

1       8. The allegations of paragraph 8 of the Complaint set forth legal conclusions to  
2 which no response is required. To the extent that paragraph 8 of the Complaint sets forth factual  
3 allegations to which a response is required, SenoRx denies that it has committed, or intends to  
4 commit, acts of infringement in this District, and any and all other allegations set forth in  
5 paragraph 8 of the Complaint.

## **ANSWER TO INTRADISTRICT ASSIGNMENT**

7        9.        The allegations of paragraph 9 of the Complaint set forth legal conclusions to  
8 which no response is required. To the extent that paragraph 9 of the Complaint sets forth factual  
9 allegations to which a response is required, SenoRx admits that this purports to be an intellectual  
10 property action that is subject to assignment on a District-wide basis pursuant to Civil Local Rule  
11 3-2(c).

## **ANSWER TO BACKGROUND**

13       10.     SenoRx is without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations set forth in paragraph 10 of the Complaint, and on that basis denies the  
15 allegations.

16        11.     SenoRx is without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations set forth in paragraph 11 of the Complaint, and on that basis denies the  
18 allegations.

19       12. SenoRx is without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations set forth in paragraph 12 of the Complaint, and on that basis denies the  
21 allegations.

22       13. SenoRx admits that the term brachytherapy has been used to refer to radiation  
23 therapy in which the radiation source is in proximity to the tissue being treated. SenoRx is  
24 without knowledge or information sufficient to form a belief as to the truth of the other allegations  
25 set forth in paragraph 13 of the Complaint, and on that basis denies any and all other allegations in  
26 that paragraph.

27        14. SenoRx admits that a 510(k) Summary of Safety and Effectiveness, specifying a  
28 device name “MammoSite™ Radiation Therapy System (RTS),” control number K011690, was

1 date-stamped by the FDA on May 6, 2002. SenoRx denies any and all other allegations set forth  
2 in paragraph 14 of the Complaint.

3       15. SenoRx admits that the Patents-In-Suit are the subject of this Complaint, but denies  
4 that the patents were validly issued and denies any and all other allegations set forth in paragraph  
5 15 of the Complaint.

6       16. SenoRx admits, on information and belief, that Cytac Corp. acquired Proxima  
7 Therapeutics in 2005, and that Hologic, Inc. combined with Cytac Corp. in 2007. SenoRx is  
8 without knowledge or information sufficient to form a belief as to the truth of the other allegations  
9 set forth in paragraph 16 of the Complaint, and on that basis denies any and all other allegations in  
10 that paragraph.

11       17. SenoRx admits that it submitted a premarket notification under section 510(k) of  
12 the Food, Drug and Cosmetic Act for a device for implementing breast brachytherapy, specifying  
13 the device name “SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy.” The  
14 remaining allegations of paragraph 17 of the Complaint set forth legal conclusions to which no  
15 response is required. To the extent that paragraph 17 of the Complaint sets forth further factual  
16 allegations to which a response is required, SenoRx denies any and all other allegations set forth in  
17 paragraph 17 of the Complaint.

18       18. SenoRx admits that the FDA approved its premarket notification on or about May  
19 18, 2007. The section 510(k) summary (No. K071229), attached as Exhibit D to the Complaint,  
20 speaks for itself. SenoRx denies that the MammoSite® Radiation Therapy System is claimed by  
21 the Patents-In-Suit, and denies any and all other allegations set forth in paragraph 18 of the  
22 Complaint.

23       19. SenoRx admits that it refers to the SenoRad device by, inter alia, the tradename  
24 “Contura™ Multi-Lumen Balloon.” To the extent that paragraph 19 of the Complaint sets forth  
25 further factual allegations to which a response is required, SenoRx denies any and all other  
26 allegations set forth in paragraph 19 of the Complaint.

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**ANSWER TO COUNT ONE – INFRINGEMENT OF U.S. PATENT NO. 5,913,813**

20. In response to paragraph 20 of the Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 19 of the Complaint as if fully set forth herein.
21. SenoRx denies the allegations set forth in paragraph 21 of the Complaint.
22. SenoRx denies the allegations set forth in paragraph 22 of the Complaint.
23. SenoRx denies the allegations set forth in paragraph 23 of the Complaint.
24. SenoRx denies the allegations set forth in paragraph 24 of the Complaint.
25. SenoRx denies the allegations set forth in paragraph 25 of the Complaint.
26. SenoRx denies the allegations set forth in paragraph 26 of the Complaint.

**ANSWER TO COUNT TWO – INFRINGEMENT OF U.S. PATENT NO. 6,413,204**

27. In response to paragraph 27 of the Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 26 of the Complaint as if fully set forth herein.
28. SenoRx denies the allegations set forth in paragraph 28 of the Complaint.
29. SenoRx denies the allegations set forth in paragraph 29 of the Complaint.
30. SenoRx denies the allegations set forth in paragraph 30 of the Complaint.
31. SenoRx denies the allegations set forth in paragraph 31 of the Complaint.
32. SenoRx denies the allegations set forth in paragraph 32 of the Complaint.
33. SenoRx denies the allegations set forth in paragraph 33 of the Complaint.

**ANSWER TO COUNT THREE – INFRINGEMENT OF U.S. PATENT NO. 6,482,142**

34. In response to paragraph 34 of the Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 33 of the Complaint as if fully set forth herein.
35. SenoRx denies the allegations set forth in paragraph 35 of the Complaint.
36. SenoRx denies the allegations set forth in paragraph 36 of the Complaint.
37. SenoRx denies the allegations set forth in paragraph 37 of the Complaint.
38. SenoRx denies the allegations set forth in paragraph 38 of the Complaint.
39. SenoRx denies the allegations set forth in paragraph 39 of the Complaint.
40. SenoRx denies the allegations set forth in paragraph 40 of the Complaint.

## **ANSWER TO DEMAND FOR JURY TRIAL**

2       41. The allegations of paragraph 41 of the Complaint set forth legal conclusions to  
3 which no response is required.

## **ANSWER TO PRAYER FOR RELIEF**

5       42. The “WHEREFORE” paragraph following paragraph 41 of the Complaint states  
6 Plaintiffs’ prayer for relief to which no response is required. To the extent a response is required,  
7 SenoRx denies the allegations set forth in the “WHEREFORE” paragraph following paragraph 41  
8 of the Complaint and denies that Plaintiffs are entitled to any of the relief requested therein, or to  
9 any relief whatsoever.

## **AFFIRMATIVE DEFENSES**

11 SenoRx sets forth the following affirmative and other defenses. SenoRx does not intend  
12 hereby to assume the burden of proof with respect to those matters as to which, pursuant to law,  
13 Plaintiffs bear the burden.

**FIRST DEFENSE – NONINFRINGEMENT OF U.S. PATENT NO. 5,913,813**

15        43. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products  
16 has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by  
17 inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No.  
18 5,913,813 (the “813 patent”).

**SECOND DEFENSE – NONINFRINGEMENT OF U.S. PATENT NO. 6,413,204**

20        44. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products  
21 has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by  
22 inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No.  
23 6,413,204 (the "204 patent").

**THIRD DEFENSE – NONINFRINGEMENT OF U.S. PATENT NO. 6,482,142**

25       45. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products  
26 has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by  
27 inducement, or by any theory of equivalency) any valid, enforceable claim of 6,482,142 (the "142  
28 patent").

1                   **FOURTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 5,913,813**

2       46.     Each of the claims of the '813 patent is invalid for failure to satisfy the provisions  
 3 of one or more of sections 102, 103, 112, and/or 116 of Title 35 of the United States Code.

4                   **FIFTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,413,204**

5       47.     Each of the claims of the '204 patent is invalid for failure to satisfy the provisions  
 6 of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

7                   **SIXTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,482,142**

8       48.     Each of the claims of the '142 patent is invalid for failure to satisfy the provisions  
 9 of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

10                  **COUNTERCLAIMS**

11                  Pursuant to Federal Rule of Civil Procedure 13, SenoRx, Inc. ("SenoRx"), through  
 12 undersigned counsel, brings the following counterclaims against Hologic, Inc., Cytac Corp., and  
 13 Hologic L.P.:

14                  **PARTIES**

15       49.     Defendant and Counterclaimant SenoRx, Inc. is a Delaware corporation with its  
 16 principal place of business in Aliso Viejo, California.

17       50.     On information and belief, Plaintiff and Counterdefendant Hologic, Inc. is a  
 18 Delaware corporation with its principal place of business in Bedford, Massachusetts.

19       51.     On information and belief, Plaintiff and Counterdefendant Cytac Corp. is a  
 20 Delaware corporation with its principal place of business in Marlborough, Massachusetts.

21       52.     On information and belief, Plaintiff and Counterdefendant Hologic L.P. is a limited  
 22 partnership with its principal place of business in Marlborough, Massachusetts.

23                  **JURISDICTION AND VENUE**

24       53.     These counterclaims arise under the patent laws of the United States, 35 U.S.C. §§  
 25 101, et seq. and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202. This  
 26 Court has jurisdiction under the laws of the United States concerning patents, and 28 U.S.C. §§  
 27 1331, 1338(a), and 1367.

28       54.     Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

**COUNT ONE – DECLARATORY JUDGMENT OF  
NONINFRINGEMENT OF U.S. PATENT NO. 5,913,813**

55. SenoRx hereby incorporates paragraphs 1 through 54 of its Answer and Counterclaims as if fully set forth herein.

56. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No. 5,913,813 (the "813 patent").

**COUNT TWO – DECLARATORY JUDGMENT OF  
NONINFRINGEMENT OF U.S. PATENT NO. 6,413,204**

57. SenoRx hereby incorporates paragraphs 1 through 56 of its Answer and Counterclaims as if fully set forth herein.

58. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No. 6,413,204 (the "204 patent").

**COUNT THREE – DECLARATORY JUDGMENT OF  
NONINFRINGEMENT OF U.S. PATENT NO. 6,482,142**

59. SenoRx hereby incorporates paragraphs 1 through 58 of its Answer and Counterclaims as if fully set forth herein.

60. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No. 6,482,142 (the "142 patent").

**COUNT FOUR – DECLARATORY JUDGMENT OF  
INVALIDITY OF U.S. PATENT NO. 5,913,813**

61. SenoRx hereby incorporates paragraphs 1 through 60 of its Answer and Counterclaims as if fully set forth herein.

62. Each of the claims of the '813 patent is invalid for failure to satisfy the provisions of one or more of sections 102, 103, and/or 112 of Title 35 of the United States Code.

**COUNT FIVE – DECLARATORY JUDGMENT OF  
INVALIDITY OF U.S. PATENT NO. 6,413,204**

63. SenoRx hereby incorporates paragraphs 1 through 62 of its Answer and Counterclaims as if fully set forth herein.

64. Each of the claims of the '204 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

**COUNT SIX – DECLARATORY JUDGMENT OF  
INVALIDITY OF U.S. PATENT NO. 6,482,142**

65. SenoRx hereby incorporates paragraphs 1 through 64 of its Answer and Counterclaims as if fully set forth herein.

66. Each of the claims of the '142 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

## COUNT SEVEN – EXCEPTIONAL CASE

67. SenoRx hereby incorporates paragraphs 1 through 66 of its Answer and Counterclaims as if fully set forth herein.

68. The facts and circumstances of this case warrant a finding that it is an exceptional case pursuant to 35 U.S.C. § 285.

## **PRAYER FOR RELIEF**

WHEREFORE, Defendant and Counterclaimant SenoRx, Inc. requests the following relief:

- (a) Plaintiffs' Complaint be dismissed with prejudice;
  - (b) The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products be declared not to infringe any claim of the '813 patent;
  - (c) The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products be declared not to infringe any claim of the '204 patent;
  - (d) The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products be declared not to infringe any claim of the '142 patent;
  - (e) The claims of the '813 patent be declared invalid;
  - (f) The claims of the '204 patent be declared invalid;

- 1 (g) The claims of the '142 patent be declared invalid;  
2 (h) The case be judged to be exceptional pursuant to 35 U.S.C. § 285;  
3 (i) SenoRx be awarded its reasonable attorneys' fees, expenses, and costs; and  
4 (j) SenoRx be awarded such other and further relief as this Court may deem just and  
5 proper.

**DEMAND FOR TRIAL BY JURY**

7 According to Federal Rule of Civil Procedure 38, Defendant and Counterclaimant SenoRx,  
8 Inc. hereby demands a trial by jury of the issues in the attached Answer and Counterclaims.

10 | Dated: February 27, 2008

**WILSON SONSINI GOODRICH & ROSATI**  
Professional Corporation

By: s/ F.T. Alexandra Mahaney  
F.T. Alexandra Mahaney  
amahaney@wsgr.com

Attorneys for Defendant and Counterclaimant  
**SENRX, INC.**

CERTIFICATE OF SERVICE  
U.S. District Court, Northern District of California,  
*Hologic, Inc. et al. v. SenoRx, Inc.*  
Case No. C-08-00133 RMW

4 I, Liz C. Bojorquez, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

7 On February 27, 2008, I served a copy(ies) of the following document(s):

**DEFENDANT SENORX, INC.'S ANSWER TO COMPLAINT;  
COUNTERCLAIMANT SENORX, INC.'S COUNTERCLAIMS  
FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY AND  
NON-INFRINGEMENT; DEMAND FOR JURY TRIAL**

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

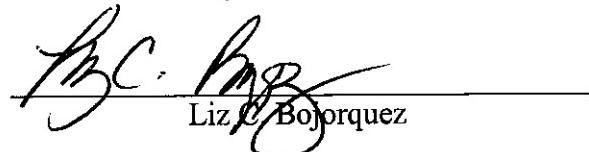
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HOLOGIC, INC. CYTYC  
CORPORATION and  
HOLOGIC LP

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(BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

- 1       (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s), to the  
2      addressee(s) noted above, designated by the express service carrier for collection and  
3      overnight delivery by following the ordinary business practices of Wilson Sonsini  
4      Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily  
5      familiar with WSGR's practice for collecting and processing of correspondence for  
6      overnight delivery, said practice being that, in the ordinary course of business,  
7      correspondence for overnight delivery is deposited with delivery fees paid or provided for  
at the carrier's express service offices for next-day delivery the same day as the  
correspondence is placed for collection.
- 6       (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case  
7      Management/Electronic Case File system with the U.S. District Court for the Northern  
District of California.

8                  I declare under penalty of perjury under the laws of the United States that the above is true  
9      and correct, and that this declaration was executed on February 27, 2008.

10                   
11                 Liz C. Bojorquez

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